

(19)



Europäisches Patentamt

European Patent Office

Office européen des brevets



(11)

EP 0 721 742 A1

(12)

EUROPEAN PATENT APPLICATION

(43) Date of publication:

17.07.1996 Bulletin 1996/29

(51) Int. Cl.⁶: **A23L 1/30**, A23L 1/302,
A23L 1/304, A23L 1/305

(21) Application number: **96200047.7**

(22) Date of filing: **10.01.1996**

(84) Designated Contracting States:

**AT BE CH DE DK ES FR GB GR IE IT LI LU NL PT
SE**

(30) Priority: **13.01.1995 US 372558**

(71) Applicant: **CLINTEC NUTRITION COMPANY,
AN ILLINOIS PARTNERSHIP
Deerfield, IL. 60015-0760 (US)**

(72) Inventors:

- **Chang, Shen-Youn**
Wadsworth, IL 60083 (US)
- **Kruzel, Chris**
Wheeling, IL 60090 (US)
- **Lin, Paul**
Fullerton, CA 92633 (US)

(74) Representative: **Vuille, Roman et al**
Avenue Nestlé 55
CH-1800 Vevey (CH)

(54) Nutrition for elderly patients

(57) This provides a composition and method for providing nutrition to elderly patients. The composition includes a protein source providing at least 16% of the calories of the composition, a lipid source, and a carbohydrate source. The carbohydrate source includes a source of dietary fiber including a balance of soluble to insoluble fiber ratio of approximately 1:3. The composition also includes increased levels of certain vitamins and minerals.

EP 0 721 742 A1

Description

This invention relates generally to compositions and methods for the treatment and nutritional support of patients. More specifically, this invention relates to nutrition for elderly patients.

Americans greater than 65 years old were, at the turn of the century, 4% of the population; currently, they are greater than 12% of the population. Though only 12% of the population, the elderly account for greater than 40% of acute hospital bed days, buy greater than 30% of all prescription drugs and spend 30% of the greater than 600 billion dollar US health budget. Still further, it is estimated that in 2030, greater than 70 million Americans (1:5) will be over the age of 65, and the "over 85's" are expected to experience the highest percentage increase of all. The Merck Manual, 16th Edition, p. 2540.

As the average age of the population increases, obtaining a better understanding of the unique aspects of ageing in relation to nutritional needs and treatment is imperative. Many physiologic functions decline progressively throughout adult life and have an impact on nutrition. For instance, a reduction in the number of functioning cells and the resultant slowing of metabolic processes results in a decrease in caloric requirements among the elderly. Also, the reduction in physical activity that generally accompanies ageing further decreases energy requirements.

Merely decreasing the total caloric intake of an elderly patient may adversely affect the required nutrition of the patient. When the total caloric intake is reduced, the remaining food intake must carefully insure a properly balanced intake of proteins, vitamins and minerals. To reduce caloric intake in the elderly, consumption of "empty" calories (i.e. fats) must be reduced and consumption of nutrient-dense foods (i.e. carbohydrates and proteins) must be increased.

While the nutritional needs of the mature adult patient differ from adult patients, in the health care settings, standard nutritional formulas are the primary form of elemental nutrition currently being used for the elderly. Naturally, standard formulas do not take into account the known nutritional needs of the elderly patients. These standard nutritional products must be supplemented with key micronutrients to compensate for common deficiencies and metabolic changes of the elderly patient. Moreover, since the elderly have a diminished capacity to manage a fluid load, standard formulas must be modified to produce a calorically dense formulation that will provide increased energy and nutrition with a minimum amount of fluid.

Therefore, a need exists for a nutritional formula designed to meet the nutritional needs of elderly patients.

In one aspect, this invention provides the use of a protein source for the preparation of a composition which further contains a carbohydrate source; and a lipid source including a mixture of medium and long chain triglycerides and in which the protein source provides at least 18% of the total calories of the composition; for providing nutrition to an elderly patient.

In another aspect, this invention provides the use of a carbohydrate source which includes a source of dietary fiber having a soluble fiber to insoluble fiber ratio of about 1:4 to 4:1; for the preparation of a composition which further contains a protein source; and a lipid source including a mixture of medium and long chain triglycerides; for providing nutrition to an elderly patient.

In another aspect, this invention provides the use of a vitamin and mineral source for the preparation of a composition which further contains a protein source; a carbohydrate source and a lipid source including a mixture of medium and long chain triglycerides and in which the vitamin and mineral source includes the following vitamins and minerals in the amounts: about 120 to 300 mg/L of Vitamin C; about 15 to 30 mg/L of Zinc; about 400 to 800 mg/L of Vitamin D; about 60 to 180 mg/L of Vitamin E; about 3000 to 6000 IU/L of Vitamin A; about 400 to 1600 mg/L of Folic acid; about 2 to 8 mg/L of Vitamin B₆; about 6 to 18 mg/L of Vitamin B₁₂; about 1.5 to 3 mg/L of Thiamine; about 1.7 to 3.5 mg/L of Riboflavin; about 800 to 1600 mg/L of Calcium; and about 50 to 150 mg/L of Selenium; for providing nutrition to an elderly patient. These are key vitamin and minerals found to be deficient in the institutionalized elderly.

In a further aspect, this invention provides a composition for providing nutrition to an elderly patient; the composition comprising:

a protein source in an amount to provide 16% to 25% of the total calories of the composition (preferably at least 18% of the total calories);

a carbohydrate source which includes a source of dietary fiber having a soluble fiber to insoluble fiber ratio of about 1:4 to about 4:1 (preferably about 1:3); and

a lipid source including a mixture of medium and long chain triglycerides.

Preferably, the carbohydrate source provides 48% to 55% of the total calories of the composition. More preferably, the soluble fiber constitutes approximately 30% of the dietary fiber source.

Preferably, lipid source provides about 26% to about 36% of the total calories of the composition. Further, the long chain triglycerides are preferably selected to provide a ratio of omega-6 (n-6) to omega-3 (n-3) fatty acids of about 4:1 to about 10:1.

The composition preferably includes a source of beta-carotene; for example in an amount of about 2 to about 10 mg/L. Further, the composition preferably provides at least 100% of the USRDA of vitamins and minerals.

Preferably the composition has a caloric density of approximately 1.2 kcal/ml.

In use, an effective amount of the composition is administered to an elderly patient.

In an embodiment, the composition includes increased levels of key vitamins and minerals found to be deficient in the institutionalized elderly. Specifically, the composition includes increased levels of vitamin C, zinc, vitamin D, vitamin E, vitamin A, folic acid, vitamin B₆, vitamin B₁₂, thiamine, riboflavin, calcium and selenium.

An advantage of the composition is that it is ready-to-use, nutritionally complete, and contains proteins, lipids, carbohydrates and vitamins and minerals in proportions appropriate for elderly patients.

Moreover, an advantage of the composition is that it provides a nutritional diet for tube and oral use designed for optimal tolerance and absorption in elderly patients.

Another advantage of the composition is that it contains higher levels of key micronutrients to compensate for common deficiencies and metabolic changes in elderly when compared with standard formulas.

Furthermore, an advantage of the composition is that it eliminates the need for vitamin supplementation and meets regulatory requirements of the elderly.

Yet another advantage of the composition is that it includes an ideal fiber balance to promote good bowel function in ageing patients. More specifically, the ideal fiber level avoids constipation and prevents impaction.

Still another advantage of the composition has increased protein levels to account for the increased needs often found in the institutionalized elderly. The composition addresses the increased repletion requirements for protein-energy malnutrition in the older patient.

Moreover, an advantage of the composition is that it provides a calorically dense formulation that allows for increased energy and nutrition with a minimal amount of fluid. Uniquely, the composition meets or exceeds U.S. RDA for vitamin and minerals in one liter. As a result, the composition is appropriate for fluid-restricted patients and is designed to accommodate slower gastric emptying, which may be seen in the elderly.

Additional features and advantages of the present invention are described in, and will be apparent from, the detailed description of the presently preferred embodiments.

Nutritional support of elderly requires prevention, recognition and treatment of nutritional depletion that may occur with ageing and illness. The composition and methods of this invention are designed specifically to provide nutritional support to elderly patients. In this regard, the composition is designed to meet the energy needs of an elderly patient in a reduced volume.

The protein source of the composition provides approximately 16% to 25% of the total calories of the composition. In an embodiment, the protein source is caseinate. In an embodiment, the protein source comprises at least 18% of the total calories of the composition. Relative to calorie needs, the elderly patient needs an increased amount of protein. Therefore, the composition includes slightly higher protein levels than standard formulas to account for increased needs often found in the institutionalized elderly.

The inventors believe that the increased protein in the composition helps correct the protein-energy malnutrition often found in elderly patients. The higher intake of protein may correct immunologic deficiencies associated with protein depletion. Moreover, the higher intake may prevent skin breakdown, which is highly correlated with protein depletion. Still further, the higher protein level promotes more rapid restoration of body protein stores that decrease with age.

Carbohydrates provide approximately 48% to 55% of the caloric content of the composition. In an embodiment, a carbohydrate source provides approximately 52% of the caloric content of the composition. Carbohydrates are an important energy source for the elderly patient as they are readily absorbed and utilized. A number of carbohydrates can be used including maltodextrin or sucrose.

In addition to simple sugars, the carbohydrate source, in an embodiment, includes a source of dietary fiber. Numerous types of dietary fiber are available. Dietary fiber passes through the small intestine undigested by enzymes and represents a kind of natural and necessary laxative. Suitable sources of dietary fiber, among others, include soy, oat or gum arabic.

The total fiber contained in the composition is approximately 8 to 15 g/L. While fiber is necessary for the elderly population since constipation is a chronic problem, the composition contains less total fiber than other products to alleviate problems associated with impaction and the increased water requirements associated with high amounts of fiber. Some older adults may not easily tolerate large amounts of fiber without adaptation. In fact, patients on narcotics or with ultramotility may be at risk for bowel obstruction, especially with the administration of excess fibers. Moreover, high fiber intake may bind calcium, reducing absorption; particularly given the high incidence of atrophic gastritis in the elderly. In a preferred embodiment, the composition includes approximately 10 g/L of total fiber.

In an embodiment, the dietary fiber is a mixture of soluble and insoluble fiber. The inventors believe that a mixture of soluble and insoluble fibers may prevent or reduce constipation and lower serum cholesterol and blood glucose in the elderly. In an embodiment, the soluble to insoluble ratio of the composition is approximately 4:1 to 1:4. In a preferred embodiment, the soluble to insoluble fiber ratio is approximately 1:3.

In the soluble/insoluble mixture, soluble fiber provides gut fuel by providing short chain free fatty acids in the large intestine. Additionally, the inventors believe that soluble fiber retains moisture. As a result thereof, while the total amount of fiber provided by the composition is less than other standard products, the amount of soluble fiber provided is higher.

The lipid source of the composition includes a mixture of medium chain triglycerides (MCT) and long chain triglycerides (LCT). The lipid source provides is approximately 26% to about 36% of the caloric content of the composition. In an embodiment, the lipid source provides approximately 30% of the caloric content of the composition.

The lipid source includes at least 20% from medium chain triglycerides. Such medium chain triglycerides are easily absorbed and metabolized in the elderly patient's body. The remainder of the lipid source is a mixture of long chain triglycerides. Suitable sources of long chain triglycerides are canola oil, corn oil, soy lecithin and residual milk fat. The lipid profile containing such long chain triglycerides is designed to have a polyunsaturated fatty acid omega-6 (n-6) to omega-3 (n-3) ratio of approximately 4:1 to 10:1. The proposed ratio of n-6:n-3 is designed to prevent suppression of the immune system caused by excessive n-6 fatty acids.

In an embodiment, the composition includes a source of beta-carotene. Beta-carotene meets a portion of the required vitamin A, thereby meeting micronutrient requirements in a small caloric volume. It is also an important nutrient with anti-oxidant properties. For example, it may reduce or mitigate symptoms of heart disease in ageing adults. Adequate amounts of beta-carotene may also protect against cataracts. The composition preferably includes approximately 2 to 10 mg/L of beta-carotene. In an embodiment, beta-carotene is present in an amount of approximately 6 mg/L.

Still further, the composition, in an embodiment, includes a specialized vitamin and mineral profile. The composition includes at least 100% of the USRDA of all vitamins and minerals. Moreover, the composition includes higher levels of the key vitamins and minerals found to be deficient in the institutionalized elderly. Vitamin-mineral deficiencies are often associated with protein-energy malnutrition in the elderly. The increased levels of vitamins and minerals exceed U.S. RDA (for normal, healthy adults) to meet the enhanced needs of the geriatric adults. As a result, utilizing the composition eliminates the need for vitamin and mineral supplementation.

Specifically, the composition preferably includes increased levels of vitamin C, zinc, vitamin D, vitamin E, vitamin A, folic acid, vitamin B₆, vitamin B₁₂, thiamine, riboflavin, calcium, and selenium.

Vitamin C is preferably present in an amount of approximately 120 to 300 mg/L. Blood levels of vitamin C tend to decline with age. In fact, greater than 40% of elderly may take in less than half of the U.S. RDA for vitamin C. Even mild deficiencies may play a role in the pathogenesis of declining neurocognitive function in ageing adults. Increased doses may be associated with increased immune function and exert a protective effect against cancer, heart disease and cataracts. In an embodiment, vitamin C is present in an amount of approximately 240 mg/L.

Zinc is necessary to maintain skin integrity, rate of epithelialization and collagen strength. Since intake and intestinal absorption decrease with age, low serum levels have been documented in the elderly. Supplementation with adequate zinc has been shown to restore immune function. The composition includes from approximately 15 to 30 mg/L of zinc. In an embodiment, zinc is present in an amount of approximately 24 mg/L.

Vitamin D is necessary for adequate phosphorous absorption. Likewise, calcium absorption is impaired in the elderly and higher levels of vitamin D help with absorption and decrease hyperthyroidism. Still further, a deficiency of vitamin D caused by lack of sun exposure may be common in the institutionalized elderly. Moreover, current RDA of the vitamin may be too low for the elderly to maintain serum parathyroid hormone concentrations and healthy bone mass. The composition includes from approximately 400 to 800 IU/L of vitamin D. In an embodiment, vitamin D is present in approximately 600 IU/L.

Vitamin E acts as an antioxidant and may protect against age-related accumulation of free-radical reactions and greater lipid peroxidation that may contribute to degeneration and disease. Supplementation with vitamin E has been shown to enhance cell-mediated immunity in the elderly. The composition includes from approximately 60 to 180 IU/L of vitamin E. In an embodiment, vitamin E is present in an amount of approximately 100 IU/L.

The amount of vitamin A, also an antioxidant, is increased as compared with other similar formulas. Vitamin A acts as a free radical scavenger and is present in the composition in approximately 3000 to 6000 IU/L. In an embodiment, vitamin A is present in approximately 4000 IU/L.

Vitamin B₆ and folic acid are at increased levels because vitamin B₆ and folic acid absorption in the elderly is inefficient. Also, there is a high degree of deficiency of these in the elderly population. In fact, vitamin B₆ deficiency has been associated with neurological changes and immunocompetence in the elderly. The composition includes from approximately 2 to 8 mg/L of vitamin B₆ and approximately 400 to 1600 mg/L of folic acid. In an embodiment, vitamin B₆ and folic acid are present in amounts of approximately 4 mg/L and 1200 mg/L, respectively.

Vitamin B₁₂ is at an increased level in the composition due to deficiencies in the elderly from atrophic gastritis and impaired absorption. Serum B₁₂ is known to decline with age. The composition includes from approximately 6 to 18 mg/L of vitamin B₁₂. In an embodiment, vitamin B₁₂ is present in an amount of approximately 12 mg/L.

Thiamine (B₁) transmits impulses for central and peripheral nerve cell function. Decreased intake of thiamine may be associated with neuromuscular malfunctions and heart failure. The composition includes from approximately 1.5 to 3 mg/L of thiamine. In an embodiment, thiamine is present in an amount of approximately 2.25 mg/L.

Adequate amounts of riboflavin (B₂), the level of which is also increased in the composition, are required for proper energy and protein utilization. Deficiency of riboflavin may result in skin breakdown. The composition includes from approximately 1.7 to 3.5 mg/L of riboflavin. In an embodiment, riboflavin is present in an amount of approximately 2.55 mg/L.

As stated above, calcium absorption is impaired in the elderly. Thus, increased levels of calcium are included in the composition of the present invention. Calcium is required for tissue repair. Moreover, calcium is important in slowing/preventing bone loss in postmenopausal osteoporosis. Increased intake may be required for adequate calcium balance. The composition includes from approximately 800 to 1600 mg/L of calcium. In an embodiment, calcium is present in an amount of approximately 1250 mg/L.

Still further, selenium is at an increased level in the composition. Selenium acts as an anti-oxidant and an immune stimulant. It also has some anti-inflammatory action. The composition includes from approximately 50 to 150 mg/L of selenium. In an embodiment, selenium is present in an amount of approximately 80 mg/L.

The composition is a ready-to-use enteral formulation. The composition can be used as a supplement or for total enteral nutritional support. The composition can be tube-fed to a patient, or fed by having the patient drink it. Preferably, the caloric density of the composition is 1.2 kcal/ml and yields a non-protein calorie-to-nitrogen ratio of 114:1 to promote positive nitrogen balance.

By way of example, and not limitation, an example of a suitable composition that may be used is as follows:

The composition includes the following ingredients: protein: caseinate; carbohydrate: maltodextrin; fat: canola oil, corn oil, soy lecithin, and residue milk fat; dietary fiber; water; vitamin A; beta-carotene; vitamin D; vitamin E; vitamin K; vitamin C; thiamine (B₁); riboflavin (B₂); niacin; vitamin B₆; folic acid; pantothenic acid; vitamin B₁₂; biotin; choline; taurine; carnitine; calcium; phosphorus; magnesium; zinc; iron; copper; manganese; iodine; sodium; potassium; chloride; chromium; molybdenum; and selenium.

The composition has the following nutrient composition (per 1200 calories):

Nutrient Composition	Amount	% U.S. RDA*
Protein	54 g	120
Carbohydrate	156 g	**
Fat***	40.6 g	**
Dietary Fiber	10	**
Water	742 ml	**
Vitamin A	4000 IU	280*****
Beta-Carotene	6 mg	**
Vitamin D	600 IU	150
Vitamin E	100 IU	333
Vitamin K	80 mcg	**
Vitamin C	240 mg	400
Thiamine (B ₁)	2.25 mg	150
Riboflavin (B ₂)	2.55 mg	150
Niacin	40 mg	200

Vitamin B ₆	4 mg	200
Folic Acid	1200 mcg	300
Pantothenic Acid	15 mg	150
Vitamin B ₁₂	12 mcg	200
Biotin	400 mcg	133
Choline	452 mg	**
Taurine	100 mg	**
Carnitine	100 mg	**
Calcium	1250 mg	125
Phosphorus	1000 mg	100
Magnesium	400 mg	100
Zinc	24 mg	160
Iron	18 mg	100
Copper	2 mg	100
Magnesium	4 mg	**
Iodine	150 mcg	100
Sodium	763 mg	**
Potassium	1560 mg	**
Chloride	1296 mg	**
Chromium	100 mcg	**

Molybdenum	150 mcg	**
Selenium	80 mcg	**

- * U.S. Recommended Daily Allowance for Adults and Children 4 or More Years of Age
- ** U.S. RDA Not Established.
- *** MCT Provides 8.12 Grams
- **** Vitamin A Calculated As a Combination of Retinol (80% of U.S. RDA per 1000 ml) Plus Beta-Carotene. Conversion of Beta-Carotene to Retinol Occurs in the Body Up to a Maximum of 10,000 IU per 100 ml (200% of U.S. RDA).

It will be understood that various modifications to the presently preferred embodiments described herein will be apparent to those skilled in the art. Such changes and modifications can be made without departing from the spirit and scope of this invention and without diminishing its attendant advantages. It is therefore intended that such changes and modifications be covered by the appended claims.

Claims

1. The use of a protein source for the preparation of a composition which further contains a carbohydrate source; and a lipid source including a mixture of medium and long chain triglycerides and in which the protein source provides at least 18% of the total calories of the composition; for providing nutrition to an elderly patient.
2. The use of a carbohydrate source which includes a source of dietary fiber having a soluble fiber to insoluble fiber ratio of about 1:4 to 4:1; for the preparation of a composition which further contains a protein source; and a lipid source including a mixture of medium and long chain triglycerides; for providing nutrition to an elderly patient.
3. The use of a vitamin and mineral source for the preparation of a composition which further contains a protein source; a carbohydrate source and a lipid source including a mixture of medium and long chain triglycerides and in which the vitamin and mineral source includes the following vitamins and minerals in the amounts:

Vitamin C	120 to 300 mg/L
Zinc	15 to 30 mg/L
Vitamin D	400 to 800 mg/L
Vitamin E	60 to 180 mg/L
Vitamin A	3000 to 6000 IU/L
Folic acid	400 to 1600 mg/L
Vitamin B ₆	2 to 8 mg/L
Vitamin B ₁₂	6 to 18 mg/L
Thiamine	1.5 to 3 mg/L
Riboflavin	1.7 to 3.5 mg/L
Calcium	800 to 1600 mg/L
Selenium	50 to 150 mg/L;

for providing nutrition to an elderly patient.

4. A composition for providing nutrition to an elderly patient; the composition comprising:
 a protein source in an amount to provide 16% to 25% of the total calories of the composition;
 a carbohydrate source which includes a source of dietary fiber having a soluble fiber to insoluble fiber ratio of about 1:4 to 4:1; and
 a lipid source including a mixture of medium and long chain triglycerides.
5. The use or composition according to any of claims 1, 2 and 4 in which the composition includes the following vitamins and minerals:

Vitamin C	120 to 300 mg/L
Zinc	15 to 30 mg/L
Vitamin D	400 to 800 mg/L
Vitamin E	60 to 180 mg/L
Vitamin A	3000 to 6000 IU/L
Folic acid	400 to 1600 mg/L
Vitamin B ₆	2 to 8 mg/L
Vitamin B ₁₂	6 to 18 mg/L
Thiamine	1.5 to 3 mg/L
Riboflavin	1.7 to 3.5 mg/L
Calcium	800 to 1600 mg/L
Selenium	50 to 150 mg/L.

6. The use of claim 2 or claim 3 in which the protein source provides at least 18% of the calories of the composition.

7. The use according to claim 1 or claim 3 in which the carbohydrate source includes a source of dietary fiber having a soluble fiber to insoluble fiber ratio of approximately 1:4 to 4:1.
8. The use or composition according to any of claims 1 to 7 in which the long chain triglycerides are selected to provide a ratio of n-6 to n-3 fatty acids of 4:1 to 10:1.
9. The use or composition according to any of claims 1 to 8 in which the composition includes a source of beta-carotene.
10. The use or composition according to any of claims 1 to 9 in which the composition has a caloric density of approximately 1.2 kcal/ml.



European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 96 20 0047

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X A	WO-A-88 01861 (BAXTER TRAVENOL) * page 14, line 15-19; claims 1,2,12,32 *	1 2-10	A23L1/30 A23L1/302
X A	US-A-5 221 668 (M.F.HENNINGFIELD ET AL.) * column 5, line 55-56; claims; table I II *	1,10 2-9	A23L1/304 A23L1/305
A	EP-A-0 614 616 (CLINTEC) * claims *	1-10	
A	WO-A-94 28734 (A.F.CZAP) * claims 1-5,8,9 *	1-10	
A	WO-A-94 27628 (ABBOT) * claims; tables *	1-10	
			TECHNICAL FIELDS SEARCHED (Int.Cl.6)
			A23L
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 13 March 1996	Examiner Van Moer, A
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document</p>			

EPO FORM 150 (3.92) (P4C01)